IN THE CLAIMS:

Please cancel claims 4, 6, 10-12, 14, 18 and 20 without prejudice.

Please amend claim 19 as follows:

12 ~~19~~. (Amended) The method of claim ~~13~~ 8, [further comprising multiple intradermal administrations] wherein said vaccine is administered every 4 weeks.

REMARKS

Reconsideration of this application is respectfully requested.

Upon entry of this amendment, claims 1-3, 5, 7, 8, 9, 13, 15, 16, 17 and 19 are pending in this application. Applicant gratefully acknowledges the Examiner's indication that claims 1-3, 5, 7, 13, and 15 have been allowed. Claims 4, 6, 10-12, 14, 18 and 20 have been canceled. Claim 19 has been amended.

Rejection Under 35 U.S.C. § 251:

Claims 4, 6, 8-12, 14, and 16-20 have been rejected as being based upon new matter added to the patent for which reissue is sought. Claims 4, 6, 10-12, 14, 18 and 20 have been canceled without prejudice. With respect to these claims, the rejection is moot. With respect to claims 8, 9, 16, 17 and 19, Applicant respectfully traverses the rejection.

Claims 8 and 16 recite a method in which the claimed vaccine is administered to post-surgical melanoma patients. The Examiner states the specification fails to provide support for this limitation at col. 5, lines 43-44, as originally indicated by the Applicant. In fact, support

for claims 8 and 16 can be found at col. 5, **lines 32-35.** The specification at col. 5, lines 32-35 discloses that "in post-surgical adjuvant patients, there was a highly significant correlation between the intensity of delayed-type hypersensitivity (DTH) to autologous melanoma cells and the time to recurrence of tumor." DTH to melanoma cells is induced by the administration of the haptenized tumor vaccine of the invention (see e.g., specification at col. 3, lines 11-13). Thus, to obtain the statistical correlation results in post-surgical patients, which results are disclosed in col. 5 lines 32-35, the post-surgical melanoma patients had to be immunized with the vaccine of the invention, as recited in claims 8 and 16. Thus, post-surgical administration of the claimed vaccine is disclosed by the specification of the prior '551 patent. Accordingly, the rejection of claims 8 and 16 is believed not to be proper. Withdrawal of the rejection is respectfully requested.

Claims 9 and 17 recite a method of the invention in which the claimed vaccine is administered to stage four melanoma patients. The Examiner rejects claims 9 and 17 as containing new matter primarily on the ground that the '551 patent does not clearly teach that the vaccine was administered after the patients were characterized as having stage four melanoma as opposed to patients entering the stage four melanoma after the beginning of treatment. Applicant respectfully disagrees. The specification of the prior patent discloses the administration of the claimed vaccine to patients with stage four melanoma at col. 5, lines 1-11. Therein, the specification discloses vaccination results and teaches that patients had regression of metastases in skin, nodes, lung and liver upon vaccine administration. Patients with lung and liver metastasis are characterized as stage four melanoma patients. See, e.g., Stadelmann and Reintar,

Hematol. Oncol. Clin. North Am. 12(4):767-796, 1998 (copy enclosed, see pages 785-791, and particularly highlighted text on page 787.) The fact that these patients were indeed stage four melanoma patients prior to vaccination (as opposed to patients that entered stage four after vaccine administration) is evident from the disclosure at col. 5, lines 1-11. In this portion of the specification, Applicant described results obtained with two groups of patients: first group (lines 2-6) having regression in multiple metastases including lung and liver metastases (stage four melanoma patients) and second group (lines 6-11) having regression in metastases that appeared after the beginning of vaccination. The two patient groups were separate as is clear from lines 6-11, which teach that "[i]n 6 additional patients,...the regression of metastitic lesions that appeared after the immunotherapy" was observed (emphasis added). The specification defines this type of regression as "delayed" regression (col. 5, lines 10-11) in obvious contrast to the regression of metastases existing prior to vaccination (which is described in the previous sentence at col. 5, lines 1-6). Thus, the specification teaches administration of the vaccine to stage four melanoma patients and resulting regression of their pre-vaccine skin, node, liver and lung metastases as well as administration of the vaccine to patients that experienced additional metastatic lesion after beginning of the treatments.

Claim 19 has been amended to delete the recitation of "multiple intradermal administrations," which recitation the Examiner believes not to be supported by the specification. While the Applicant respectfully disagrees, the amendment is made to expedite the prosecution of this reissue application. Withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph:

Claims 4, 6, 8-12, 14, and 16-20 have been rejected as containing subject matter which was not described in the specification. Claims 4, 6, 10-12, 14, 18 and 20 have been canceled without prejudice and claim 19 has been amended. The rejection with respect to these claims is now moot.

Claims 8 and 16 recite a method in which the claimed vaccine is administered to post-surgical melanoma patients. Claims 8 and 16 are described by the specification for the reasons indicated under the response to the new matter rejection.

Claims 9 and 17 recite a method in which the claimed vaccine is administered to stage four melanoma patients. The subject matter of these claims is described by the patent specification for the reasons indicated under the response to the new matter rejection.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, 1st ¶ is believed to be in order and is respectfully requested.

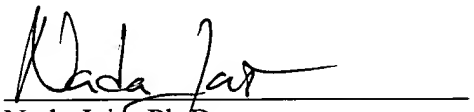
Rejection Under 35 U.S.C. § 112, Second Paragraph:

Claims 4, 10, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4, 10, and 18 have been canceled without prejudice and are no longer at issue in this application.

Conclusion:

In view of the above amendments and remarks, claims 1-3, 5, 7, 8, 9, 13, 15, 16, 17 and 19 are believed to be in condition for allowance. A Notice to that effect is respectfully requested.

Respectfully submitted,



Nada Jain, Ph.D.
Reg. No. 41,431
Attorney for Applicants

DARBY & DARBY, P.C.
805 Third Avenue
New York, N.Y. 10022
Phone (212) 527-7700